

**In the United States Patent and Trademark Office
Before the Board of Patent Appeals and Interferences**

Appl. No. : 10/544,154 Confirmation No. 6432
Applicant : Francis X. Smith et al.
Filed : August 1, 2005 Art Unit: 1612
Title : L-HISTIDINE IN OPHTHALMIC SOLUTIONS
Examiner : Basquill, Sean M.
Docket No. : 3009099 US01
Customer No. : 44,331

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APPEAL BRIEF FOR APPLICANT PURSUANT TO 37 C.F.R. 41.37
AND 35 U.S.C. 134

Sir:

Appellants hereby appeal to the Board of Patent Appeals and Interferences from the Examiner's Final Rejection of claims 1-20 which was contained in the Office Action mailed December 3, 2009.

A timely Notice of Appeal in compliance with 37 CFR 41.31 was filed June 3, 2010 along with the Pre-Appeal Brief Request for Review.

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APPELLANT'S BRIEF ON APPEAL

II. Real Party In Interest

The real party in interest is the assignee of the application, FXS Ventures, LLC, having a place of business in the city of Salem, New Hampshire.

III. Related Appeals and Interferences

An appeal was filed in U.S. Pat. Appl. No. 11/613,061, which is a continuing application from this pending application, on November 24, 2010.

IV. Status of the Claims

Claims 1-20 are pending in the application.

Claims 1-20 are rejected.

Claims 1-20 are hereby appealed.

Appendix I provides a clean, double spaced copy of the claims on appeal.

V. Status of Amendments

A response after Final, including only remarks, was filed on April 5, 2010, subsequent to the Final Rejection. An Advisory Action dated August 18, 2010 was then received indicating that the Examiner considered, but did not find that the remarks were sufficiently persuasive to place the Application in condition for allowance. A Pre-Appeal Brief Request for Review was filed on June 3, 2010. A Notice of Panel Decision from Pre-Appeal Brief Review was received June 29, 2010 rejecting claim 1-20.

VI. Summary of Claimed Subject Matter

The invention relates to an ophthalmic solution, a method for supplying a rinsing solution and a method for treating a contact lens, the solution containing L-histidine, hydrogen peroxide and a cationic polymeric preservative, the solution having improved preservative efficacy against fungal contamination.

Independent claim 1 recites an ophthalmic solution (Para. [0028]) having 0.01 to about 1.0 percent by weight L-histidine (Para. [0028]); 0.0001 to 0.01 percent by weight

hydrogen peroxide (Para. [0028]); and 0.1 to 500 parts per million of a cationic polymeric preservative (Para. [0028]).

Independent claim 2 recites a method for supplying a rinsing solution to an eye (Para. [0002]) having the step of contacting an eye with a solution (Para. [0028]) having 0.01 to about 1.0 percent by weight L-histidine (Para. [0028]); 0.0001 to 0.01 percent by weight hydrogen peroxide (Para. [0028]); and 0.1 to 500 parts per million of a cationic polymeric preservative (Para. [0028]).

VII. Grounds of Rejection to be Reviewed on Appeal

The following issue is presented for review by the Board of Patent Appeals and Interferences:

1. Whether claims 1-3 and 5-20 are unpatentable under 35 § U.S.C. 103(a) over Mowrey-McKee et al. (U.S. Patent No. 5,817,277) in view of Chowhan et al. (U.S. Patent No. 5,741,817).
2. Whether claims 1-20 are unpatentable under 35 § U.S.C. 103(a) over Mowrey-McKee et al. (U.S. Patent No. 5,817,277) as modified by Chowhan et al. (U.S. Patent No. 5,741,817) and further in view of Han et al. (U.S. Patent No. 5,620,970).

VIII. Arguments

Rejection of Claims 1-3 and 5-20 under 35 U.S.C. § 103(a):

As discussed in detail below, the Final Office Action dated December 3, 2009 fails to set forth a *prima facie* case of obviousness to sustain a rejection of claims 1-3 and 5-20. In section 2 of the Office Action dated December 3, 2009, claims 1-3 and 5-20 stand rejected under 35 § U.S.C. 103(a) as being unpatentable over Mowrey-McKee et al. (U.S. Patent No. 5,817,277) in view of Chowhan et al. This rejection is respectfully urged as in error for at least the following reasons.

The Advisory Action dated April 19, 2010 indicates that the remarks file on April 5, 2010 have been considered but that they do not put the application in condition for allowance. The Examiner indicates that Chowhan et al. (U.S. Patent No. 5,741,817) cannot logically teach away from the use of EDTA because the reference discloses that

EDTA is used within the ophthalmic art. However, applicants arguments set forth in the request for reconsideration filed April 5, 2010 have been misconstrued.

Application contests that combining a reference that utilizes EDTA with Chowhan frustrates the purpose of the Chowhan reference. It is well established that if a proposed modification would render the reference unsatisfactory for its intended purpose, then the combination is not proper. *In re Gordon*, 733 F.2d 900 (Fed. Cir. 1984). When viewing Chowhan et al. as a whole, the reference explicitly indicates that the ophthalmic solution should not contain EDTA. While the Examiner indicates that the use of EDTA is well-known in the art, Chowhan et al. explicitly indicates that the ophthalmic solutions disclosed should not contain EDTA because of the risk to damage of corneal cells. In determining the differences between reference and the claims, the question is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious. *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530 (Fed. Cir. 1983). Furthermore, a prior art reference must be considered in its entirety, even including portions of the reference that would lead away from the claimed invention. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540 (Fed. Cir. 1983). It has been established that where the teachings of two or more prior art references conflict, the examiner consider the degree to which one reference might accurately discredit another. *In re Young*, 927 F.2d 588 (Fed. Cir. 1991). In the instant matter, when viewing Chowhan as a whole, one of ordinary skill in the art would be influenced to create a solution without EDTA present. Therefore, combining Chowhan with a reference that teaches a solution containing EDTA in order to substantiate an obviousness rejection is improper as the proposed combination frustrates the purpose of the Chowhan reference.

As discussed above, combination of the teachings of Mowrey-McKee et al. with the teachings of Chowhan et al. is improper. The proposed combination frustrates the purpose of Chowhan et al. The stated purpose of Chowhan et al. is to produce an ophthalmic composition that does not contain EDTA. *See*, Col. 1, Lns. 29-33; Col. 1, Lns. 50-58; Col. 3, Lns. 22-23; and Cl. 1. If a proposed modification would render the reference unsatisfactory for its intended purpose, then the combination is not proper. *In re Gordon*. By contrast, Mowrey-McKee et al. discloses utilizing EDTA as a preferred component of the ophthalmic solution. Here Chowhan et al. and Mowrey-McKee et al.

are in stark contrast to one another, and when viewing Chowhan et al. as a whole, the proposed modification frustrates the purpose of the reference thereby rendering the combination improper.

Further, Mowrey-McKee et al. does not describe L-histidine in an ophthalmic solution. The Examiner relies on Chowhan et al. to teach this limitation, indicating that it would be obvious to include low molecular weight amino acids to improve the efficacy of antimicrobial preservatives in ophthalmic solutions. However, Chowhan et al. lacks sufficient specificity to teach one skilled in the art the use of L-histidine. The instant claims are specifically limited to the inclusion of L-histidine. By contrast, Chowhan et al. discloses a sizable list of suitable amino acids, with the only guidance given being a preference for low molecular weight amino acids which include alpha (α) carboxylic acid groups, and a preferred embodiment utilizing glycine. Similar to the fact that a claimed species is encompassed by a prior art genus is not sufficient by itself to establish a *prima facie* case of obviousness (*In re Baird*, 16 F.3d 380 (Fed. Cir. 1994)), so to should the lack of specificity within a list of suitable compounds be unable to support a *prima facie* case of obviousness. When looking at Chowhan et al. as a whole, the only preferred compound listed in the examples and the specification is glycine. Other than the preference for glycine, a person of ordinary skill in the art has no guidance in selecting suitable compounds,.

Finally, the instant claims provide surprising results. The specific combination of L-histidine with a very low level of hydrogen peroxide in the presence of preservative improves the antifungal properties of ophthalmic solutions. As shown in example 3 of the specification as originally filed, the samples containing both L-histidine and hydrogen peroxide provide superior antifungal properties when compared to the solutions without hydrogen peroxide.

For these reasons, it is believed that the instant claims are non-obvious over Mowrey-McKee et al. and Chowhan et al., and that this rejection should be reversed.

Rejection of Claims 1-20 under 35 U.S.C. § 103(a):

In section 3 of the Office Action dated December 3, 2009, claims 1-20 stand rejected under 35 § U.S.C. 103(a) as being unpatentable over Mowrey-McKee et al. as

modified by Chowhan et al. as applied to claims 1-3 and 5-20 above, and further in view of Han et al. (U.S. Patent No. 5,620,970). This rejection is respectfully urged as in error.

As discussed above, one skilled in the art would not combine the solution of Mowrey-McKee et al. as modified by the solution of Chowhan et al. Additionally, claims 3-20 benefit from dependency of claims 1 and 2, which as discussed above, are patentable. Therefore, it is respectfully requested that this rejection be reversed.


IX. Summary

The combination of the teachings of Mowrey-McKee et al. with the teachings of Chowhan et al. is improper. The proposed combination frustrates the purpose of Chowhan et al. when viewed as a whole. Furthermore the instant claims provide surprising results in that the combination of L-histidine with a very low level of hydrogen peroxide in the presence of preservative improves the antifungal properties of ophthalmic solutions. Therefore, it is respectfully urged that the rejection be reversed.

X. Conclusion

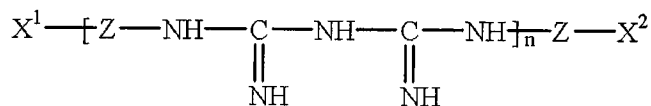
For the above reasons, Appellants respectfully request that the Board of Patent Appeals and Interferences reverse the rejection by the Examiner and mandate the allowance of claims 1-20.

Respectfully submitted,
HISCOCK & BARCLAY, LLP

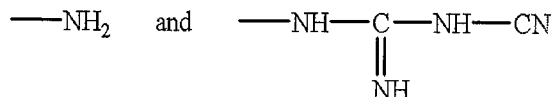
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XI. Appendix I - Claims on Appeal

1. An ophthalmic solution comprising:
0.01 to about 1.0 percent by weight L-histidine;
0.0001 to 0.01 percent by weight hydrogen peroxide; and
0.1 to 500 parts per million of a cationic polymeric preservative.
2. A method for supplying a rinsing solution to an eye comprising the step of:
Contacting an eye with a solution comprising:
0.01 to about 1.0 percent by weight L-histidine;
0.0001 to 0.01 percent by weight hydrogen peroxide; and
0.1 to 500 parts per million of a cationic polymeric preservative.
3. The ophthalmic solution of claim 1 further comprising a surface-active agent.
4. The ophthalmic solution of claim 3, wherein said surface-active agent is a hydroxy-ethoxylated castor oil.
5. The ophthalmic solution of claim 1, wherein said cationic polymeric preservative is a polymeric biguanide.
6. The ophthalmic solution of claim 1, wherein said cationic polymeric preservative is represented by the following formula:



wherein Z is an organic divalent bridging group, n is from 1 to 500, and X¹ and X² are:



7. The ophthalmic solution of claim 6, wherein said cationic polymeric preservative has a number average molecular weight of at least 1,000.
8. The ophthalmic solution of claim 1 further comprising about 0.00001 to about 0.5 weight percent of a germicidal agent.
9. The ophthalmic solution of claim 1 having a pH between 6.0 and 8.0.
10. The ophthalmic solution of claim 1 having a pH between 6.5 and 7.8.
11. The ophthalmic solution of claim 1 further comprising 0.05 to 2.5 weight percent of a buffer.
12. The ophthalmic solution of claim 11, wherein said buffer is selected from the group consisting of boric acid, sodium borate, potassium citrate, citric acid, sodium bicarbonate, bis-tris propane, TRIS, mixed phosphate buffers and mixtures thereof.
13. The ophthalmic solution of claim 1 further comprising a tonicity agent.
14. The ophthalmic solution of claim 1 further comprising a chelating agent selected from the group consisting of ethylenediaminetetraacetic acid, nitrilotriacetic acid, diethylenetriamine pentaacetic acid, hydroxyethylethylenediaminetriacetic acid, 1,2-diaminocyclohexanetetraacetic acid, ethylene glycol bis (beta-aminoethyl ether) in N, N, N', N' tetraacetic acid (EGTA), aminodiacetic acid, hydroxyethylamino diacetic acid, salts of ethylenediaminetetraacetic acid and disodium edetate.
15. The ophthalmic solution of claim 1 having a tonicity between 240 and 310 mOsm/kg.
16. The ophthalmic solution of claim 1 further comprising between 0.01 and 0.35 weight percent sodium chloride.

17. The ophthalmic solution of claim 1 further comprising between 0.01 to about 15 weight percent of a surfactant.
18. The method for supplying a rinsing solution of claim 2, wherein said solution has a pH between 6.5 and 7.8
19. The method for supplying a rinsing solution of claim 2, wherein said cationic polymeric preservative is a polymeric biguanide.
20. The method for supplying a rinsing solution of claim 2, wherein said solution further comprises between 0.01 and 0.35 weight percent sodium chloride.

XII. Appendix II - Evidence

None

Appendix III – Related Proceedings

U.S. Pat. Appl. No. 11/613,061